Pharmacy

Controlled Substances Policy

A prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner; however, it's important to note that a corresponding responsibility rests with the pharmacist who fills the prescription. Technicians and interns also play a role in supporting this effort in each of our pharmacies.

Please review the following Publix policy concerning the dispensing of controlled substances in the pharmacy. This policy covers the following:

- Identifying Invalid Controlled Substance Prescriptions, including:
  - Overview
  - Prescription Requirements
  - Minimizing Risks
  - Handling and Reporting
- Prescription Drug Monitoring Programs (PDMP)
- Loss Prevention Investigations
- Losses and Theft of Controlled Substances

When you are done reviewing this policy, please click the "Yes" button on the completion screen. **By clicking "Yes", you are acknowledging that you have read and understand Publix's Controlled Substances Policy.**

This information is also located on the Pharmacy Portal in Chapter 8 of the *Pharmacy R&P Guide*, see: ***Pharmacy → References → Pharmacy R&P Guide.***

If you have any questions about this policy, please contact your Pharmacy Supervisor.

Identifying Invalid Controlled Substance Prescriptions - Overview

Introduction

It's important to comply with Drug Enforcement Agency (DEA) and state regulations regarding the dispensing of controlled substances not only for the safety of your patients, but also to minimize consequences for Publix and Publix associates. To that end, Publix Pharmacy is committed to minimizing the dispensing of controlled substances based on fraudulent representations which is the focus of this policy.

Your responsibility

Fraudulent representations are situations where a prescription is deceptively presented to your pharmacy as a valid prescription when in reality it is an invalid prescription. An *invalid prescription* is one that a pharmacist knows or has reason to know was not issued for a legitimate medical purpose.

You are responsible for minimizing the dispensing of controlled substances based on fraudulent representations. This responsibility includes

- identifying and guarding against invalid practitioner-patient relationships
- guarding against filling fraudulent prescriptions for controlled substances
- identifying prescriptions that are communicated or transmitted illegally to avoid filling them
- identifying the characteristics of a forged or altered prescription to avoid filling them

Identifying Invalid Controlled Substance Prescriptions – Prescription Requirements

Introduction

To identify suspicious or fraudulent prescriptions, it's important to understand requirements associated with controlled substance prescriptions.

Requirements for controlled substance prescriptions

Pharmacy associates should know the requirements for a controlled substance prescription.

Schedule II

Schedule II prescriptions may be dispensed if the original hard copy of the written, signed prescription is presented to the pharmacy or if the pharmacy receives an e-prescription (see **Electronic transmission** section below).

See the DEA's website for the Code of Federal Regulations, section 1306.11, for exceptions. There are situations where a fax or oral prescriptions may be appropriate, but there are specific DEA requirements for handling these situations.

Also, refer to your state regulations.

Other Schedules

Schedule III, IV and V prescriptions may be dispensed with receipt of a written prescription, fax received directly from the prescriber's office, an oral prescription, or an e-prescribed prescription (see **Electronic transmission** section below).

See the DEA's website for the Code of Federal Regulations, section 1306.21, for exceptions.

Also, refer to your state regulations.

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Identifying Invalid Controlled Substance Prescriptions – Prescription Requirements, Continued

Electronic transmission

Electronic Prescribing for Controlled Substances (EPCS) was developed by the DEA to provide pharmacies and prescribers with the ability to use traditional e-Prescribing with additional security measures to order new (Schedule II-V) and submit refill requests (Schedule III-V) for controlled substances. EPCS helps streamline the process to reduce risk of fraud and abuse from stolen prescription pads and/or forgery.

Not all Prescribers have the ability to electronically send and receive controlled substance prescriptions. Only the prescribers setup with the certified ePrescribing software, and who are individually certified can send and receive EPCS prescriptions.

When a new prescription is sent, before it enters workflow there are validation checks to make sure that the prescriber and prescription are valid.

Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing

Introduction

To minimize the dispensing of controlled substances based on fraudulent representations, it's important for a pharmacy associate to first identify suspicious or fraudulent prescription activity. If a pharmacy associate discovers a suspicious or fraudulent controlled substance prescription the pharmacist on duty should be notified and the prescription should not be filled until its validity can be verified.

Examples of suspicious activity or prescriptions

Always use professional judgment when assessing situations; however, consider this list of potential suspicious activity that may indicate an invalid controlled substance prescription is being presented to you in the pharmacy.

- The prescriber's practice is not near where the patient resides.
- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area.
- The patient appears impaired or his/her behavior is suspicious.
- The patient appears to be returning too frequently. (A prescription which should have lasted for a month in legitimate use, is being refilled on a biweekly, weekly or even a daily basis.)
- The patient requests early refills or states that the previous fill was lost or stolen.
- The patient changes prescribers frequently ("doctor shopping").
- The patient has multiple controlled substance prescriptions.
- A new patient presents a prescription for a large quantity of a controlled substance.
- The patient only pays cash for controlled substance prescriptions.
- The prescriber writes prescriptions for central nervous system (CNS) drugs, such as depressants and stimulants, at the same time. Some drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of patients appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- Numerous people who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same physician.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Types of fraudulent activity or prescriptions

Always use professional judgment when assessing situations; however, consider this list of potential ways that a fraudulent controlled substance prescription may be presented to you in the pharmacy.

- For those prescriptions required to be written on tamper resistant paper, a legitimate tamper resistant prescription pad could be stolen from a physician's office and used to write prescriptions for fictitious patients.
- A prescription could be altered by a patient in an effort to obtain additional amounts of legitimately prescribed drugs.
- A prescription pad from a legitimate doctor could be printed with a different call-back number where a drug abuser or accomplice verifies the prescription.
- A prescription could be called in by a drug abuser or accomplice providing their own telephone number as a call back confirmation.
- A prescription could be created from a home computer or a copy of a prescriber's legitimate prescription.

Identifying & guarding against invalid practitioner-patient relationships

Pharmacy associates should know how to identify an invalid practitioner-patient relationship. Some ways to do this are

- checking the prescriber's address to determine if it is the same general area as the patient's address
- checking the state's Prescription Drug Monitoring Program (PDMP) database to determine information such as frequency of fills, use of particular prescribers, dispensing of excessive quantities, filling at multiple pharmacies, etc.

  Note: If the pharmacy receives notice from the Florida PDMP program that within any 90-day period the patient has received prescriptions for controlled substances from more than one prescriber and had these prescriptions filled by five or more pharmacies, this indicates drug abuse as set forth in Rule 64K-1.007, FAC
- looking up the prescriber's contact information via another source and contacting the prescriber directly to validate the prescription.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Guarding against filling fraudulent prescriptions

Pharmacy associates should take the following actions in reviewing a controlled substance prescription.

- Carefully examine controlled substance prescriptions against the DEA and state requirements (see pg. 8-47).
- Evaluate that any faxed, transmitted, or orally prescribed prescriptions meet DEA and state requirements (see pg.8-47).
- Verify that controlled substance prescriptions are written on the required tamper resistant form when required by law.

  Note: For Florida, use the Approved Vendor Verification link on the Pharmacy page to assist you.
- Check the prescription to determine whether any information on the prescription has been altered.
- Check the prescriber's signature to make sure that it appears legitimate.
- For oral prescriptions, verify that the call came from the prescriber's office (e.g., if unsure or suspicious, call the office back using the phone number from our records).
- For oral prescriptions, verify that the caller is on the prescriber's staff (e.g., if unsure or suspicious, call the office back using the phone number from our records).
- For faxed prescriptions, make sure that the fax transmission came directly from the prescriber's office.
- Call the prescriber using the number on file if there are any questions.
- At pick-up, check the person's identification and verify that it is the person named on the prescription.

  Note: The states of Florida, South Carolina and North Carolina have more strict guidelines and are required to capture identification numbers in the pharmacy system. Reference **PDMP Reporting Requirements** on pg. 8-55 for further details. Also, see **Acceptable Photo ID's** on the pharmacy portal page @ *References→ Government/Agency→ Boards of Pharmacy & Government Agencies*.

Identifying prescriptions communicated or transmitted illegally

Pharmacy associates should carefully examine written, faxed or transmitted controlled substance prescriptions to try to ascertain if they are legitimate. Refer to the guidance in the above section, **Guarding against filling fraudulent prescriptions,** on pg. 8-51.

Note: All Florida and Georgia controlled substance prescriptions are required to be on tamper resistant prescription paper. Tennessee further requires all prescriptions to be on tamper resistant prescription paper. Also, CMS requires that all Medicaid prescriptions be on tamper resistant prescription paper – see more in the section on **Tamper-Resistant Prescription Pads** on pg. 8-41.

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Identifying Invalid Controlled Substance Prescriptions – Minimizing Risk of Dispensing, Continued

Identifying characteristics of a forged or altered prescriptions

Pharmacy associates should be able to identify characteristics of a forged or altered prescription. Some ways to do this are to determine if the

- prescription looks "too good" - the prescriber's handwriting is too legible
- prescription does not comply with the acceptable standard abbreviations or appear to be textbook presentations
- prescription appears to be photocopied
- directions are written in full with no abbreviations
- person other than the patient attempts to fill the prescription
- prescription is written in different color inks or written in different handwriting, or
- prescription is often paid for in cash.

Identifying Invalid Controlled Substance Prescriptions – Handling and Reporting

Introduction

It's important to properly handle a suspected invalid controlled substance prescription to protect Publix and comply with the law.

Handling a suspected invalid prescription

A pharmacy associate shall immediately notify the pharmacist on duty of any discovery of an attempt to obtain or instance where controlled substance was obtained through fraudulent methods or representations.

To determine validity of a prescription, the pharmacist must

- initiate communication with the patient or patient's representative to acquire appropriate information to determine validity, and
- initiate communication with the prescriber or prescriber's representative to acquire appropriate information to determine validity.

The pharmacist should also access the state PDMP website to acquire relevant information to determine validity.

If the pharmacist, using professional judgement, determines the prescription is invalid or cannot determine validity, the pharmacist shall refuse to fill or dispense the prescription.

Note: Pharmacists in Florida must complete a BoP-approved 2-hour continuing education (CE) course on the validation of prescriptions for controlled substances and counts toward the CE needed for license renewal.

Reporting of fraudulent prescriptions

Upon learning of any instance in which a person obtained or attempted to obtain from the pharmacy a controlled substance through fraudulent methods or representations, ensure the pharmacist on duty is notified. Then, the pharmacist on duty must notify the Pharmacy Supervisor.

Prescription Drug Monitoring Programs (PDMP)

About PDMP

Each state we operate in has developed a Prescription Drug Monitoring Program (PDMP), which is an online database established to record all controlled substance prescriptions filled in the particular state. The database gives pharmacists the ability to look at a patient's purchase history of controlled substances. Pharmacists can then use the information to make professional judgments about whether or not to fill a controlled substance for a patient.

Publix expectations for PDMP use

In the state of Florida, pharmacists must check the PDMP website prior to dispensing CII, CIII, CIV, and opioid CV (including refills) to patients 16 years and older.

In the state of Tennessee, pharmacists must check the PDMP Prior to dispensing a new opioid or benzodiazepine scheduled as a CII-CV.

In all other states, Publix Pharmacists must at a minimum create a personal account and use the website database to identify whether or not dispensing certain controlled substance prescriptions is appropriate. Some circumstances where using the database is recommended are listed below:

- new patient to Publix with a prescription for a large quantity of a controlled substance
- patient paying cash for controlled substance prescriptions
- patient with multiple controlled substance prescriptions
- patient requesting early refill or stating a previous fill was lost or stolen
- patient appears impaired or behavior is suspicious
- any time you feel in your professional judgment as a Pharmacist that it is necessary to check the patient's history

You can access the PDMP for your state from your EnterpriseRx home page, under: *Links→ Reference Links→* [*State*] *Prescription Drug Monitoring Program*.

PDMP Reporting Requirements

Each state has different requirements for reporting to the PDMP. Florida, South Carolina and North Carolina law incorporates a requirement to check and capture photo identification information at pick-up in certain situations. This has been integrated into EnterpriseRx in the form of a pop-up at Release to Patient (RTP).

In this step, you will be required to capture pick-up person's name, identification type, number and jurisdiction, as well as relationship to the patient.

For Florida, you can refer to the FL Retail Pharmacy Controlled Substance Law Update and the FL Hospital Pharmacy Controlled Substance Law Update for detailed information. These are located on the pharmacy portal page @ *References→ Government/Agency→ Boards of Pharmacy & Government Agencies*

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Prescription Drug Monitoring Programs (PDMP), Continued

Handling PDMP results

When referencing the PDMP database use your professional/clinical judgement, regarding how to handle a prescription.

In Florida, if you choose to fill the prescription after reviewing the patient's history in the database, document your decision in a Tx Note.

- If you choose to fill the prescription, document your decision as "PDMP Checked- RX Accepted" in a Tx Note..
- If you choose not to fill the prescription and this is an *existing customer*, document your decision as "PDMP Checked- RX Rejected" in a Tx Note.
- If you choose not to fill the prescription and this is not an existing customer who is not in our system, no further action is needed.

If you are unable to check the PDMP due to the system being down or other technical issue, be sure to document "Unable to Check PDMP- System down/ Technical issue" in a Tx Note. In this case, Florida is limited to a max of a 3-day supply as required by law. Use your best judgement for all other states.

In Tennessee, since the PDMP must be checked for first fills. The following notes should be used but documented in an *RX Note*:

- "PDMP Checked- RX Accepted": if you choose to fill the prescription after checking the PDMP.
- "PDMP Checked- RX Rejected": if you choose to not fill the prescription after checking the PDMP.
- "Unable to Check PDMP- System down/ Technical issue": if the system is down or there is a technical issue. In this situation in the state of Tennessee, the pharmacist needs to use judgement regarding the decision to dispense or not considering other parameters.

Never print or provide the patient a copy of their Patient Advisory Report (PAR), which is generated from the database by practitioners/dispensers and contains controlled substance dispensing information for a specific patient. It is for informational purposes only.

Loss Prevention Investigations

Introduction

As part of an investigation, a Publix Loss Prevention Specialist may request a minimum necessary amount of an associate's prescription information from the Pharmacy. Providing an associate's prescription information is an allowable disclosure of PHI under the Privacy Rules, as it is considered part of health care operations (conducting or arranging for medical review, legal, and auditing services, including fraud and abuse detection and compliance programs). The Pharmacy is not required to account for PHI disclosures of this type.

Providing an associate's prescription information to a Loss Prevention Specialist

Follow these steps to provide an associate's prescription information to a Loss Prevention Specialist.

Note: Be sure to only provide the minimum necessary amount of information needed to conduct the investigation. For example, only provide the prescription date and prescription cost if that's enough information to conduct the investigation. Do not provide the prescription name unless it is needed for the investigation and the request has been approved.

<table>
<tr><th>Step</th><th>Who</th><th>Action</th></tr>
<tr><td>1</td><td rowspan="2">Loss Prevention Specialist</td><td>Request an associate's prescription information needed to conduct an investigation. Is the prescription name needed?
<table>
<tr><th>If...</th><th>Then...</th></tr>
<tr><td>yes</td><td>contact the Pharmacy Supervisor and Privacy Officer for approval. Go to step 2.</td></tr>
<tr><td>no</td><td>go to step 3.</td></tr>
</table></td></tr>
<tr><td>2</td><td>Did the Pharmacy Supervisor and Privacy Officer approve the request for the prescription name?
<table>
<tr><th>If...</th><th>Then...</th></tr>
<tr><td>yes</td><td>the Pharmacy Supervisor will notify the Pharmacist that he or she can release the prescription name. Go to step 3.</td></tr>
<tr><td>no</td><td>the Pharmacist cannot supply the prescription name. The investigation will need to be conducted without the use of the prescription name.</td></tr>
</table></td></tr>
<tr><td>3</td><td>Pharmacist</td><td>Receive request and provide the Loss Prevention Specialist with the requested prescription information.</td></tr>
<tr><td>4</td><td>Loss Prevention Specialist</td><td>Conduct the investigation and secure the prescription information obtained during the investigation.
Note: Always store Confidential Incident Reports and all supporting documentation in a locked file cabinet.</td></tr>
</table>

Losses and Theft of Controlled Substances

Introduction

We're legally obligated to report thefts and/or significant losses of controlled substances to the DEA and the state Board of Pharmacy. Depending on state regulations, other agencies may need to be notified, including law enforcement. In addition, the event may require reporting of a PHI disclosure, insurance billing adjustments and/or adjustments of reporting to the Prescription Drug Monitoring Program.

Immediate reporting of suspected thefts and/or significant losses to the DEA

Contact your Pharmacy Supervisor to help you determine whether a loss is "significant."

Thefts and/or significant losses must be reported to the DEA within one business day of discovery. **Contact your Pharmacy Supervisor** to prepare the report. It should be a short statement that is faxed to the local DEA office.

Reporting thefts and/or significant losses to the DEA using Form 106

Once circumstances surrounding the theft and/or significant loss are clear the DEA should be notified using *DEA Form 106*. **Contact your Pharmacy Supervisor** to help you complete the *DEA Form 106*.

Note: The *DEA Form 106* can be found on the DEA website. Once on the Pharmacy page of Publix Connection, go to *References > Pharmacy Boards and Government Agencies > DEA – Diversion Control Program*. Then on the DEA's website find the DEA Form 106 in the Quick Links section. Once you begin the form it will ask for:

- your pharmacy's DEA number, and
- the pharmacy name on DEA registration.

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Losses and Theft of Controlled Substances, Continued

Reporting thefts and/or significant losses to state agencies

Once circumstances surrounding the theft and/or significant loss are clear you may be required to notify other agencies. **Contact your Pharmacy Supervisor** to help you determine this.

State	Requirements
Alabama	• In the event of a theft/significant loss, provide a copy of DEA Form 106 to the AL Board of Pharmacy. No time period for reporting is defined by rule or statute, but the expectation is that it would be reported contemporaneous with the DEA being notified. Ala. Admin. Code §680-X-3-.07. • In the event of a loss or theft of precursor chemicals, must report to the AL Board of Pharmacy no later than the 3rd business day after discovery of loss/theft. Code of Ala. §20-2-186.
Florida	• Report to the local sheriff within 24 hours after discovery of significant loss/theft. Fla. Stat. §893.07(5)(b) • Report to the FL Board of Pharmacy within 1 business day after discovery of significant loss/theft. Fla. Stat. §465.022(11)(b).
Georgia	• Immediately notify the GA Board of Pharmacy of any theft or loss of drugs or devices. This is not limited to "significant losses" nor to controlled substances. O.C.G.A. §26-4-112(4). • With respect to controlled substances, any loss or theft must be reported to the GA Board of Pharmacy and the GDNA within 72 hours of discovery. The report should be made on DEA Form 106. This is not limited to "significant losses." GDNA also requires a final report resulting from the associated audit/investigation within 72 hours of completion of the audit/investigation. Ga. Comp. R. & Regs. §480-16-.06 and §480-28-.10.
North Carolina	Report to the NC Board of Pharmacy within 10 days of the loss/theft, using the Drug Disaster and Loss Report (http://www.ncbop.org/Forms/DrugDisasterandLossReport.pdf). Statute and reporting form do not limit this to "significant losses" nor controlled substances. N.C. Gen. Stat. §90-85.25(b).
South Carolina	• Report theft or loss of drugs or devices to the SC Board of Pharmacy within 30 "working" days of discovery. S.C. Code Ann. §40-43-91(A)(1) • Report theft or any loss of controlled substances to the DHEC, Bureau of Drug Control, within 30 days of discovery. This is not limited to "significant losses". S.C. Code of Reg. R. 61-4.408. • A report of theft or "significant loss" should be submitted to DHEC on DEA Form 106. Any unexplainable losses should be reported to the supervisor.
Tennessee	Any robbery, embezzlement, theft, burglary, or fire or disaster resulting in a loss of prescription drugs, or controlled substances or medical devices or related materials must be "immediately" reported to the TN Board of Pharmacy. The report shall include a list, including amounts, of such prescription drugs or controlled substances or medical devices or related materials lost or damaged. This is not limited to "significant losses" nor to controlled substances. Tenn. Comp. R. & Regs. R. 1140-03-.09
Virginia	Upon discovery of theft or unusual loss of any controlled substance, the VA Board of Pharmacy must be immediately notified and within 30-days from discovery furnish details of the loss (e.g., list of medication, quantity, strengths). VA Pharmacy Act & Drug Control Act §54.1-3404.

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Losses and Theft of Controlled Substances, Continued

Reporting thefts and/or significant losses to Loss Prevention

Thefts and/or significant losses of controlled substances should also be reported to Publix's Loss Prevention Department with the help of your Pharmacy Supervisor. This chart provides contact information for Loss Prevention.

Division	Contact	Phone Number
Atlanta	Mike Zilleox	Office – (770) 952-6601, ext. 31734 Cell – Redacted - PII
Charlotte	Patty Morgan	Office – (704) 424-5017, ext. 71068 Cell – Redacted - PII
Jacksonville	Nolan Bomar	Office – (904) 781-8600, ext. 2478 Cell – Redacted - PII
Lakeland	Faith Clark	Office – (863) 687-7407, ext. 64510 Cell – Redacted - PII
Miami	Josh Edelstein	Office – (305) 653-1806 ext. 71339 Cell – Redacted - PII

Other reporting obligations

Thefts or significant losses can involve the disclosure of a patient's PHI. Once an incident is considered a breach or even a suspected breach, it must be reported to the Publix Privacy Officer using the Legal Event of Interest webform in the Pharmacy Operations section of the pharmacy portal page. An incident may require rebilling and re-submission of claims to the state's prescription drug monitoring program also. Discuss each scenario with your Pharmacy Supervisor to determine the appropriate action. If you need assistance with the process of rebilling or resubmission, call the Pharmacy Support Desk at 863-688-1188, x54004, option 4.